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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/822,546

04/12/2004

Mark J. Whalen

25064/104/102

1795

5909

7590

08/14/2007

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

08/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/822,546

Applicant(s)

WHALEN ET AL.

Examiner

Jeffrey G. Hoekstra

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/29/2007 has been entered.

Notice of Amendment

2. In response to the amendment filed on 05/29/2007, new claim(s) 47 is/are acknowledged. The current rejections of the claim(s) 30-46 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 30-47 are rejected under 35 U.S.C. 102(a) as being anticipated by Willard (US 5,964,732).

5. For claims 30, 34, 43, and 47, Willard discloses a method of diagnosing lower urinary tract obstructions associated with the prostatic urethra (column 1 line 56 – column 2 line 40), comprising the steps of

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- providing a diagnostic indwelling device assembly (100,100A,200,800) comprising an elongate support member slidably disposed within a lumen (101) of a physiologically responsive flexible wall segment (102) and a proximal end portion adapted to be anchored at a bladder neck of a lower urinary tract for urine ingress (column 6 lines 7-42, column 7 lines 1-10), wherein the assembly is reversibly receivable within the urethra (column 1 line 56 – column 2 line 40);
- positioning the indwelling device for selective support of a prostatic urethra (column 6 lines 9-15) such that said physiologically responsive flexible wall segment of the device transverses the prostatic urethra in furtherance of assessing prostate contribution to bladder outlet obstruction (column 1 line 56 – column 2 line 40);
- manipulating a portion of said indwelling device by sequentially and incrementally returning portions of the prostatic urethra to an unsupported condition during a bladder voiding event (column 6 lines 1-7) so as to permit a prostate to physiologically act upon a prostatic responsive segment of said indwelling device and by sequentially and incrementally retracting said elongate support member from said prostatic urethra (column 18 lines 12-45, column 25 line 19 – column 26 line 57); and
- visually assessing fluid flow (via sensing elements 112, 212) comprising urine discharge associated with said sequential and incremental return of portions of the prostatic urethra to an unsupported condition and during selective, sequential withdrawal of said elongate support member from said lumen of said diagnostic urethral device.

6. For claim 31, Willard discloses a method, wherein linear relationships among the structures of the lower urinary tract are ascertained during said sequential and incremental return of portions of the prostatic urethra to an unsupported condition (column 7 line 53 – column 9 line 19).

7. For claim 32, 39-42 and 44-46, Willard discloses a method, further comprising monitoring/assessing urine flow during said manipulating, wherein said monitoring comprises visual assessment of said urine flow character, fluid flow pressure indication and recording, quantification of discharge pressure, quantification of discharge volume (column 7 lines 24-33, column 7 line 53 – column 9 line 19).

8. For claims 33, 37, 38, Willard discloses a method, further comprising the step of obtaining a casting of the prostatic urethra, wherein said indwelling device is adapted to receive a casting agent (123) in furtherance of obtaining a casting of a prostatic urethra (column 24 lines 1-12).

9. For claims 35 and 36, Willard discloses a method, wherein said manipulating permits sequential and/or incremental assessment of prostatic urethra patency (column 1 line 56 – column 2 line 40).

Response to Arguments

10. Applicant's arguments with respect to claims 30-47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)

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272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra
Examiner, Art Unit 3736


MAX HINDENBURG
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